



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,062	10/01/2003	Alan Lombardo	62189.010701	7724

32361 7590 06/06/2006

GREENBERG TRAURIG, LLP  
MET LIFE BUILDING  
200 PARK AVENUE  
NEW YORK, NY 10166

EXAMINER
----------

SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
----------	--------------

3733

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/676,062	<b>Applicant(s)</b> LOMBARDO ET AL.	
	<b>Examiner</b> James L. Swiger	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 37-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,10-23 and 26-36 is/are rejected.
- 7) ☒ Claim(s) 4, 8-9, and 24-25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/16/05; 7/18/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 37-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/20/06.

### ***Drawings***

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are darkly shaded and some elements are not clearly drawn or clearly visible with hand-written numbers. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 103***

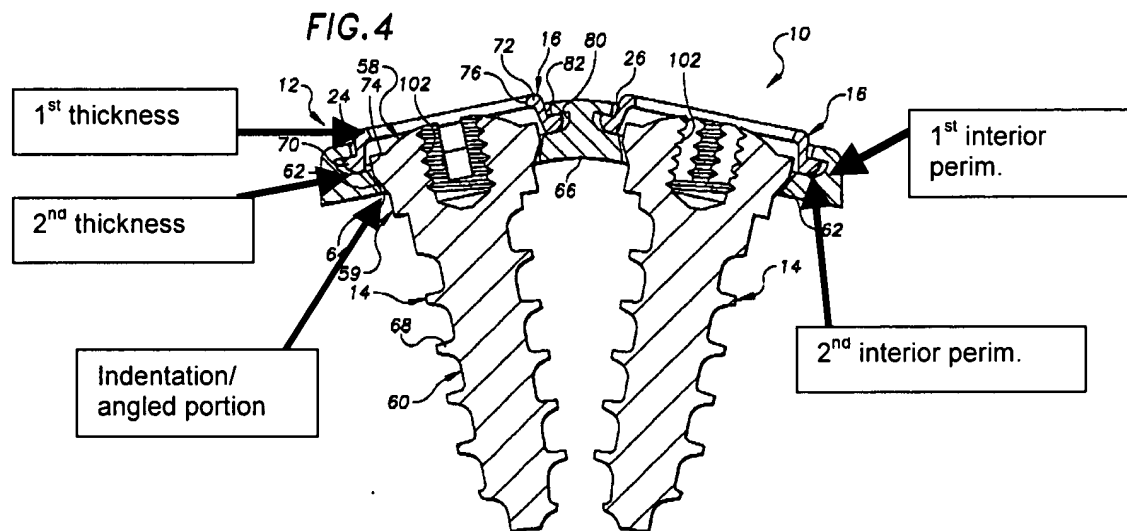
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 10-23, 26-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (US 6,599,290) in view of Farris et al (US 6,152,927). Bailey et al. disclose an implant assembly adapted to be fixed to bone comprising at least two bone screws (14; Fig. 4), having a thinner region (proximal to 59) and a thicker

Art Unit: 3733

region (58), an implant member (12) that has a top surface (84) and a bottom surface (opposite) with at least two apertures for bone screws (see Fig. 1), and has a lower region that is sized to permit the thinner region of one of the screws but not the thicker region of one of the bone screws to pass through (see profile Fig. 4; 62 and 64). This region is also adjacent to the lower surface of the implant.



Bailey et al. also disclose a washer (16), a first and second interior perimeter (see Fig. 4 above) that is disposed within the aperture of the region that has a hole large enough to allow the screw to pass through, and has a first and second thicknesses (see Fig. 4 above), and where the thicker region is in the second region (the lower portion of the implant groove shown in Fig. 4, and also the region to prevent the thicker of the screws' portions to pass through per claim 20); this may also be the lower region. At least two washers are also shown (see Fig. 4 above 16 and 12). The washer also enters the recess created by the second interior portion (see above, Fig. 4), and also has a recess where the first region may be shallower than the second (see curved portion of

Art Unit: 3733

the above figure). The bone screw is also threaded (14) and may include be considered to have grooves in the head portion of the screw. Likewise with the washer fitting into the interior perimeters, there are at least two lines of contact with the bone screw, where the screw angles downwards to substantially match the contour of the implant device. Also the implant device is capable of being used in fusing two bones. Bailey et al. also disclose a driving tool/spline for the screws (90).

Bailey et al. disclose the claimed invention except for a washer portion that enables sufficient frictional pressure, and the head of the screw contains a hex socket as a mechanism, and an implant containing up to 8 apertures. Farris et al. disclose a hex socket mechanism (55) for improved tool access (Col. 8, lines 4-10), and has a washer that provides sufficient locking and securing of the bone screw and washer (33, and Col. 3, lines 37-49). It also contains up to 8 apertures for being appropriate for the spine in use (see Col. 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Bailey et al. having at least a hex socket with a washer with sufficient frictional pressure and an implant with up to 8 apertures in view of Farris et al. to better use and secure the device.

***Allowable Subject Matter***

Claims 4, 8-9, and 24-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3733

**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 5/30/06  
JLS

  
EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER